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510(k) Summary

Submitter Information

Biosign Technologies, Inc.
100 Allstate Parkway, Suite 801
Markham ON L3R 6H3

Contact Person: Allison Scott, RAC
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Date: August 10, 2012

Trade Name: UFIT® TEN-10 Automated Wrist Blood Pressure Monitor With Computer Controls and Web Services

Common Name: Noninvasive blood pressure measurement system

Classification Name(s): System, measurement, blood-pressure, non-invasive

Classification Number: 870.1130

Predicate Device(s)

510(k) Number	Device Name	Submitter Name
K102939	iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock	Andon Health Co
K103046	Hosman USB Blood Pressure Monitor Model HM-100	Hosman International

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Device Description

UFIT® TEN-10 "Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services" is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 13.5cm-23cm.

UFIT® TEN-10 "Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services" is designed and manufactured according to ANSI/AAMI SP10-manual, electronic or automated sphygmanometers.

The operational principle is based on oscillometric method and pressure sensor technology. It calculates the systolic and diastolic blood pressure. UFIT® TEN-10 "Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services" achieves its function by connecting the device to a Personal Computer via USB connection. Furthermore the device does not contain an LCD or other display components, so it is necessary for the device to connect to a Personal Computer containing a support software to constitute a complete blood pressure measurement system.

When a reading is taken by the device through the software, it is sent through the Internet to servers that perform the analysis of the reading and the result is returned through the Internet to the end user – all by means of Cloud Computing. This provides secure accounts for the users to submit their data so that they can monitor their results and progress.

Intended Use(s)

The UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services is a non-invasive blood pressure measurement system intended to measure the systolic and diastolic blood pressure and pulse rate. It is intended for patient use at home and by healthcare professionals in their respective practice.

The device is intended for use by adults 18 years or older. The cuff is to be used for wrist sizes from 13.5 cm to 23 cm (5.3 in to 9.1 in).

Technological Characteristics

The UFIT® TEN-10 and the Hosman HM-100 have the same indications for use statement, are both used on the wrist, are connected to and powered by the USB port of a PC. The UFIT® TEN-10 and the iHealth BP3 are both intended for home and health professional use. The UFIT® TEN-10, Hosman HM-100, and iHealth BP3 all have an external display of either a PC (UFIT® TEN-10 and Hosman) or an Apple device (iHealth) and the blood pressure monitor depends on that external device to function, in that the blood pressure monitor has no function unless it is connected to the external device. Therefore, the UFIT® TEN-10 is substantially equivalent to the Hosman HM-100 and iHealth BP3.

Non-Clinical Performance Data

Non-clinical Tests have been done as follows:

Compliance to IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)

In the configuration tested, the EUT (UFIT® TEN-10) complied with the requirements of: EN 60601-1-2:2001, ICES-001 Issue 4 June 2006 and FCC 47 CFR Part 15, Subpart B – Verification

Following IEC 60601-1 (1988): Medical electrical equipment - Part 1: General requirements for safety, including Amendment 1 (1991) and Amendment 2 (1995), a representative sample of the UFIT® TEN-10 system was subjected to the test requirements of IEC 60601-1:1988, CAN/CSA C22.2 No.601.1-M90 and UL 60601-1:2003 which were conducted and witnessed at Global Advantage by CSA Certifier Mr. Peter Wong with satisfactory results.

The UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services meets all safety and performance requirements of ANSI/AAMI SP10:2002 as an automated sphygmomanometer

Clinical Performance Data

AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.

AAMI / ANSI SP10:2002/A1:2003, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

AAMI / ANSI SP10:2002/A2:2006, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services tests in accordance with ANSI/AAMI SP10, and the device meets all applicable requirements of the standard.

Non-Clinical and Clinical Performance Data Conclusions

The conclusions drawn from the tests demonstrate that UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services conforms to the standards listed above, with regards to safety, effectiveness, and performance. Substantial Equivalence is met with our predicate devices, as they too conform to these standards with regards to safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 20 2012

Biosign Technologies, Inc
c/o Allison Scott
Anson Group, LLC (USA)
9001 Wesleyan Road, suite 200
Indianapolis, IN 46268

Re: K122443
Trade Name: UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Control and Web Services
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II (two)
Product Code: DXN
Dated: October 19, 2012
Received: October 26, 2012

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: Pending

Device Name: UFIT® TEN-10 Automated Wrist Blood Pressure Monitor with Computer Controls and Web Services –

Indications For Use:

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The device is intended for use by adults 18 years or older. The cuff is to be used for wrist sizes from 13.5 cm to 23 cm (5.3 in to 9.1 in).

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
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